STATE MEDICAID DUR BOARD MEETING

THURSDAY, February 12, 2009
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125

MINUTES

Board Members Present:

Neal Catalano, R.Ph.
Tony Dalpiaz, PharmD.
Brad Hare, M.D.
Wilhelm Lehmann, M.D.
Colin VanOrman, M.D.
Derek Christensen, R.Ph.
Dominic DeRose, R.Ph.
Peter Knudson, D.D.S.
Bradley Pace, PA-C
Joseph Yau, M.D.

Board Members Excused:

Mark Balk, PharmD.
Joseph Miner, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Lisa Hulbert, R.Ph.
Merelynn Berrett, RN
Duane Parke, R.Ph.
Rick Sorenson, RN
Tim Morley, R.Ph.
Carol Runia

Other Individuals Present:

Chris Beckwith, U of U
Roy Lindfield
Marianne Paul, U of U
Michael Measom, M.D.
Tony Molchan, Abbott
Bryan Larson, U of U
Robin Campbell, Merck
Shaun Prince, Elan
Adam Westover, Pfizer
Ann Gustafson, GSK
Pat Wiseman, Medimmune
Elliott Abbott, U of U
David Pulsipher, Olag
Robert Olsen, Sciele
Jared Jensen
Barbara Roper, U of U Student
Pam Sardo, Abbott
Joe Busby, Lilly
Kate Ryan, AZ

Meeting conducted by: Colin VanOrman, M.D., DUR Board Chairman

---

1. The minutes for January 8, 2009 were reviewed, corrected, and approved. Derek noted that he did attend the January 2009 meeting, and must have forgotten to sign the role. Dr. Hare moved to approve the minutes. The motion passed with unanimous votes by Neal Catalano, Tony Dalpiaz, Dr. Hare, Dr. Lehmann, Dr. VanOrman, Derek Christensen, Dominic DeRose, Dr. Knudson, Bradley Pace, and Dr. Yau.

2. Housekeeping: Tim Morley addressed the Board. Due to budget cuts, there will not be refreshments at the DUR Board meeting. Dr. Hare noted that this was a ridiculous way to save a few dollars, when the Board is comprised of volunteers.

Lisa Hulbert was announced as a new full-time permanent Medicaid Pharmacy employee, and will be taking responsibility for the DUR Board beginning in March 2009.

3. Smoking Cessation – Class Review: Dr. Christina Beckwith from the U of U Drug Information Service presented a class review to the DUR Board that was prepared in September 2008.

Dr. Yau asked if there are safety risks associated with combination therapy, and what are the risks if patients smoke while on smoking cessation therapy? Dr. Beckwith stated that the combination therapies recommended in the guidelines are fairly low risk. For instance, the patches provide slow and steady releases of nicotine into the blood stream, while the immediate release products create a spike in nicotine levels to satisfy immediate cravings. These spikes are still lower than what would be associated with smoking.

Dr. Measom addressed the Board. He is an Addiction Psychiatrist who works in the Drug and Alcohol Unit of Valley Mental Health. Nicotine dependence is by far the number one killer for preventable deaths in adults. He is concerned about access to therapy. It is ironic when alcoholics do not want to take a particular medication due to concerns that it will harm their liver. Smoking cessation therapy is similar. The definition of efficacy is different in the varenicline studies than in the typical nicotine studies. In the varenicline studies, the definition was total abstinence for a month. In the other studies, the definition was typically reported abstinence for a week. Behavioral treatment typically doubles the success rate, and that is available for free with varenicline. The safety issues that have arisen with varenicline are of concern, but part of what happens is that people are going through withdrawals. Varenicline has only been on the market for one year, and he is continuing to monitor the safety data as reports become available. His main concern is that he wants to maintain access to be able to treat patients for nicotine dependence.

Duane Parke asked about the length of time needed to treat patients. Dr. Measom views nicotine dependence as a chronic relapsing medical condition. The studies are typically three-month studies, which is due to FDA approval requirements. Many people mistakenly believe that this means that patients should only be treated for that period of time. No one has ever done any studies to address relapse. Dr. Measom does not personally have patients on maintenance treatment, but he has had patience relapse.

Tim asked Dr. Measom if he considered it wise or unwise to request that a first-time quitter attempted nicotine replacement therapy prior to attempting Chantix. Dr. Measom stated that in the Medicaid population there is a particular problem with access and affordability. Tim Morley stated that Medicaid pays for OTC nicotine replacement therapy. Dr. Measom stated that he is impressed with the efficacy of varenicline versus the other agents, but he does not always use it as first-line therapy.

Dr. Yau asked if clients become tolerant to varenicline. Dr. Measom said that he has seen dependence and abuse with nicotine replacement therapy, but not with varenicline. The vast majority of smokers quit spontaneously.

The Board asked if there are issues with Medicaid not paying for nicotine replacement when they are supposed to. Tim asked providers to notify Medicaid when this happens.

Tim asked Dr. Beckwith to address if nicotine replacement is better than smoking. Dr. Beckwith stated that from the standpoint of public health, nicotine replacement is better than smoking because it is not associated with the other toxins found in tobacco products.

Tim stated that the Board should consider the treatment algorithm provided by the University. There are emerging safety concerns with varenicline, as well as safety concerns with bupropion and nicotine replacement. The Board should consider if a step therapy approach requiring a trial of nicotine replacement or combination therapy.

Dr. Lehmann stated that he is concerned that smoking is not a typical disorder in that requires a behavioral change. It is important to get the patient what they need when they want to change. Dr. Measom stated that patients who see him for varenicline therapy have often tried OTC products.

Tim Morley asked Dr. Beckwith if the meta-analyses that were analyzed considered the differences in the ways that efficacy was defined in the varenicline trials versus the nicotine replacement therapy trials. The meta-analyses calculated an odds ratio for smoking cessation at 6 months.

Dr. Measom stated that the definitions of abstinence and efficacy have changed, so even the weighted odds ratio is not necessarily accurate. Tim stated that the role of the DUR Board was to consider the conditional risks that may be associated with different types of therapy, as well. Dr. Measom felt that this is something that should be left up to the physician and the patient. Tim stated that Medicaid has an interest in this, since there is a cost associated with the risk of adverse events.

Neal Catalano stated that there are other cost issues, including lower cardiovascular risk, fewer doctor visits, etc. associated with a higher quite rate.

Duane asked if it would be prudent to place a "dry period" into policy for treating addiction as a chronic relapsing condition.

Dr. Lehmann asked if the 1.6 odds ratio means that the patient would be 60% more likely to quit on varenicline versus nicotine replacement therapy. Dr. Beckwith stated that the odds ratio was 1.6, but that the 95% confidence interval was 1.3 to 2.0. That means that if the same study were repeated 100 times, 95 of times the odds ratio would be in the range of 1.3-2.0. This would suggest that there is some difference, but it is probably a small one.

Dr. Knudson stated that he periodically runs into smokers who have been abstinent for 20-30 years, but have cravings when they are in a certain context. He asked if this is normal. Dr. Measom stated that this is common, and this is why behavioral therapy is needed.

Dr. Yau commented on the issue of a "dry period". This is not currently in policy for other types of addiction diagnoses, such as alcohol. It may actually be detrimental to allow for an addictive behavior to continue longer before allowing another treatment period. Dr. Measom stated that one would not restrict treatment for a diabetic because they were not compliant.

Neal asked about who would provide training and education associated with first-line nicotine replacement therapies. Tim stated that the prescriber should at least indicate to the patient about this. Neal felt that if a prescriber was busy, and the patient went to a very busy pharmacy, they might not get proper counseling. Tim stated that this could be accomplished through education. It is appropriate to educate patients and providers in using the less dangerous first-line product.

Tim stated that the way he interprets the data presented, varenicline is not much better than other products. Dr. Measom stated that the way he interprets the data, varenicline looks to be 2 times better. It also does not address the risks to public health from second and third hand smoke.

Tim Morley stated that the PA for Chantix was retired 3 months ago, and there has been an alarming increase in Chantix use since then. Medicaid is not advocating a one-time use PA again since the Board determined that does not make sense. In light of the emerging safety concerns, Medicaid is asking that the Board review the smoking cessation class. There is no question that quitting smoking reduces overall health care costs. Medicaid wants to establish the safest and most effective way to assist people in doing that.

The Board asked if there could be 3-6 months of unrestricted access before a PA is required. Dr. Measom did not feel that this was rational, since this is a chronic relapsing condition. Duane Parke added that this could not be supported by the Pharmacy POS system.

Dr. VanOrman asked Dr. Beckwith to review the criteria used to define efficacy in the various studies analyzed. Dr. Beckwith stated that there are 83 studies analyzed, so this would be a heavy commitment. She suggested a more detailed review of the meta-analyses, and determining how they pulled the data and what they used for the outcomes. This would be a good start in order to address the question of comparative efficacy. Dr. VanOrman felt that this would be necessary in order to proceed, since there is so much disagreement on the comparative efficacy of varenicline based on the studies analyzed for this meeting.

Dr. Hare stated that the algorithm provided does not have very clear guidelines for first line therapy. This is more important than cost, since the better treatment may be more expensive. However, the absence of clear guidelines makes it difficult to determine whether or not smoking cessation therapy should be an open class. If there are some agents associated with a higher cost, the DUR Board would need this information to make this decision and formulate policy.

Tim stated that this is the issue before the DUR Board. Given the information presented, does the DUR Board want to establish guidelines?

Neal moved to table the discussion until the requested information could be presented to the Board.

Dr. Measom stated that there is very little available information on step therapy for smoking cessation. Tim stated that this is why it needed to be the DUR Board's decision.

Dr. Yau asked how the Board will be able to determine which agent should be first-line given that all 7 available agents appear to carry equal recommendations. Tony felt that the decision would be based more on safety issues.

Dr. Lehmann asked what the safety issues with Chantix are. Tim stated that there is a front-line contraindication for patients with psychiatric issues with one of these agents. Dr. Lehmann asked if it is possible for the doctor to write a disclaimer about safety concerns on a prescription for Chantix or bupropion. Most clinicians would prefer to have this requirement rather than step therapy. Tim stated that this requirement would be difficult to monitor.

The Board continued to discuss the difficulties associated with developing a step therapy in the absence of clear evidence-based national guidelines.

Dr. Knudsen moved to discuss the next item on the agenda, with the possibility of returning to the issue of smoking cessation at another time. Neal seconded the motion. The motion passed with unanimous votes by Neal Catalano, Tony Dalpiaz, Dr. Hare, Dr. Lehmann, Dr. VanOrman, Derek Christensen, Dominic DeRose, Dr. Knudson, Bradley Pace, and Dr. Yau.

Next meeting set for March 12, 2009
Meeting adjourned.

The DUR Board Prior Approval Subcommittee considered 5 petitions this month.

Minutes prepared by Jennifer Zeleny